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| 10/659,802 | 09/10/2003 | Patrick Fogarty | TOSK-007CON | 5245 |

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| EXAMINER |
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MONTANARI, DAVID A

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,802

Applicant(s)

FOGARTY, PATRICK

Examiner

David Montanari

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/18/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 11-18 and 27-34 in the reply filed on 7/18/2005 is acknowledged.

2. Claims 1-10, and 19-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **WITH** traverse in Paper filed 7/18/2005.

3. Applicant's arguments filed 7/18/2005 have been fully considered but they are not persuasive.

Applicants argue in amendment that as stated in MPEP §803, if search and examination of an entire application can be made without serious burden, the examiner must examine the entire application on the merits, even though the entire application includes claims to independent or distinct inventions. Applicants continue to argue that it is their position that it would not be unduly burdensome to perform a search on all of the claims together in the present application. However, applicants argument are not persuasive. The animals made by the claimed method of group II can be made using another vector, and further the vector of group I can be used in other methods, such as introducing an exogenous DNA into a cell. The examiner would be required to search for all of the uses for the vector and kit of group I, which are not necessary for the implementation of the claimed methods, animals, and cells of group II.

The restriction requirement is still deemed proper and therefore is made FINAL.

4. Claims 11-18, and 27-34 are drawn to method of inserting an exogenous nucleic acid into the genome of a non-Drosophilidae animal, wherein said method comprises introducing into said animal a P-element derived vector comprising said exogenous nucleic acid under conditions sufficient for transposition to occur and wherein said exogenous nucleic acid is inserted into said

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genome, a method of inserting an exogenous nucleic acid into the genome of a non-Drosophilidae animal, wherein said method comprises introducing into said animal a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is in close approximation to one of the P-element transposase recognized sequences, wherein said vector comprises a transposase domain, wherein said method comprises introducing a second vector comprising a transposase domain into said animal, wherein said animal is a vertebrate, mammalian animal, or rodent, and cells from said animals that have P-element transposase recognized insertion sequences integrated into the genome and cell from said animals that have P-element transposase recognized 31 bp insertion sequences integrated into the genome.

5. Claims 11-18, and 27-34 are examined in the instant application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-17, 27-29, and 31-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 11-17, 27-29, and 31-33 encompass any transgenic organism, the scope of which encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation “non-human” would be remedial. See 1077 O.G. 24, April 21, 1987.

Double Patenting

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A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 11-18, and 27-34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 11-18, and 27-34 of copending Application No. 10/803,550.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18, and 27-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-17 of U.S. Patent No. 6,475,798 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the instant application and the patent is that

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the instant application claims also rodents using the claimed methods, wherein the patent claims all mammals, it does not specifically claim rodents using the patented method.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-18, and 27-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse, does not reasonably provide enablement for a method of inserting an exogenous nucleic acid into the genome of any non-Drosophilidae animal, wherein said method comprises introducing into said non-Drosophilidae animal a P-element derived vector comprising said exogenous nucleic acid, and cells from said non-Drosophilidae animal. The specification does not enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 11-18, and 27-34 are drawn to a method of inserting an exogenous nucleic acid into the genome of any non-Drosophilidae animal, wherein said method comprises introducing into said non-Drosophilidae animal a P-element derived vector comprising said exogenous nucleic acid under conditions sufficient for transposition to occur or a P-element vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is in close approximation to one of the P-element transposase recognized sequences, wherein said method further comprises introducing a second vector comprising a transposase domain into said animal, and cells from said non-Drosophilidae animal.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the

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state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The breadth of the claims encompasses the creation of any non-Drosophilidae transgenic animal.

Whereas the nature of the invention is a method of creating transgenic non-Drosophilidae animal, the art teaches that the field of transgenesis is unpredictable. The art teaches that transgenic mouse lines are generated by microinjection of the linear DNA of interest into the nucleus of an oocyte or transfected into embryonic stem (ES) cells, which then randomly integrates into the genome (Ristevski, *Molecular Biotechnology*, Vol. 29, 2005, pg. 159 col. 1 parag. 2 lines 1-5). Currently only mouse ES cells have been established that result in a transgenic animal (Smith, 2002, *J. of Biotechnology*, Vol. 99, pg. 3 col. 1, parag. 4 lines 1-3). With regard to transgene integration the art teaches that the site of integration is uncontrolled and yet is critical due to the possibility of integration into a silent locus. Random integration may occur, resulting in the insertional inactivation (insertional mutagenesis) of a gene at the site of integration, resulting in a loss of function that may be mistakenly attributed to over expression of the transgene (Ristevski, pg. 159 col. 1 parag. 2 lines 5-14). Further, insertional mutagenesis of a gene may not be immediately apparent if a recessive gene has been inactivated, as phenotypic abnormalities will not be evident until homozygous transgenic lines have been established (Ristevski, pg. 159 col. 1 parag. 2 lines 14-19). The site of integration may also result in altered tissue specificity, although the promoter used behaves differently at its normal chromosomal localization, with neighboring regulatory elements potentially influencing the transcriptional activity of the transgene (Ristevski, pg. 159 col. 1 parag. 3 lines 1-7). This is known as

chromosomal position effects, where host sequences surrounding the site of transgene integration can alter the expected expression pattern, turning it ectopic or not detectable (Montoliu, 2002, Cloning and Stem Cells, Vol. 4, pg 39, col. 1). With regard to copy number the art teaches that controlling the transgene copy number (usually integration is a singular event with multiple copies integrated in tandem) is also problematic in the generation of transgenic animals (Ristevski, pg. 159 col. 1 parag. 3 lines 7-11). A high tandem copy number results in a gene silencing effect, and further, is undesirable if the effect of a gene dosage is being addressed, as multiple copies will not recapitulate relevant levels of expression (Ristevski, pg. 159 col. 1 parag. 3 lines 11-14 bridge col. 2 parag. 1). With regard to transgene expression, the art teaches bluntly that, “many transgenes work poorly” (Houdebine, 2002, J. of Biotechnology, Vol. 98, pg. 150, col. 1 parag. 4 line 1). Transgene expression is often very low or not specific of the promoter added in the gene construct, and are generally attributed to position effects in chromatin as discussed above (Houdebine, pg. 150, col. 1 parag. 4 lines 1-5). The art continues to teach that a transgene is generally poorly expressed when it contains a cDNA rather than the corresponding genomic DNA sequence with its introns, has multiple copies integrated in the same site, and when a bacterial gene is used (Houdebine, pg. 150 col. 2 lines 4-9).

Overexpression of a transgene of interest also has inherent problems. This is often the case when the overproduced protein shares only a part of the properties of an endogenous protein, which can result in inhibition of the endogenous protein, by the transgene of interest working in a transdominant negative manner (Houdebine, pg. 152, col. 2 parag. 4). The art continues that the generation of transgenic animals routinely involves one of two methods of exogenous DNA delivery to the recipient cells, retroviral infection or microinjection (Smith, pgs. 5-11). However,

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each method possesses significant unpredictability for the skilled artisan to implement.

Retroviral vectors result in inconsistency and irreproducibility of transgene expression due to random integration with host DNA (Smith, pg. 6, col. 1 parag. 2), and instability due to the integrated retroviral DNA possessing the ability to spontaneously reactivate (Smith, pg. 6, col. 1 parag. 5). Microinjection of recipient cells with exogenous DNA presents the problem of mosaicism to the skilled artisan. The majority ($\approx 85\%$) of pronuclear microinjection-derived transgenic founders are mosaics of transgenic and non-transgenic cells (Smith, pg. 7, col. 2 parag. 2 lines 1-4). This becomes problematic since transmission of the transgene is dependent upon the existence and extent of germline colonization by transgene-containing cells, so that when transmission does occur, the transgene is inherited in a mendelian fashion resulting in only a small portion of the transgene being passed onto offspring (Smith, pg. 7, col. 2 parag. 3, bridge pg. 8 col. 1 lines 1-8). Significant restraints also exist for the skilled artisan attempting microinjection of other animal species other than mouse. Cow, pig, and sheep eggs are optically opaque, unlike mice, which makes microinjection of the targeted pronuclei extremely difficult (Smith, pg. 11 col. 2 parag. 1). In view of the art summarized above, the skilled artisan at the time of filing would surmise that the field of transgenesis is very unpredictable, and thus would require and undo amount of experimentation without a predictable degree of success to make and use the claimed transgenic animal.

The working examples provided by the specification teach that male mice were co-injected with a C3.1 and transposase vector via system tail vein injection (pg. 18 lines 6-14). The specification continues to teach that "Depending on the structure of the vector itself, i.e., whether or not the vector includes a region encoding a product having P element transposase activity, the

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method may further include introducing a second vector into the animal which encodes the requisite transposase activity” (pg. 11 lines 11-15). The specification continues to teach that co-injection of said vectors resulted in successful integration of the C3.1 vector in a dose-dependent manner into the genomes of said mice that was determined by PCR analysis in testis, liver, spleen, heart, lung, brain, and intestine tissue (pg. 18 lines 16-23 bridge pg. 19 lines 5-17). The specification continues to teach that said vectors were heritable when transgenic mice were bred, resulting in up to 71% of offspring being transgenic (pg. 19 lines 23-24 bridge pg. 20 lines 1-6).

However, the specification has failed to disclose a method of inserting an exogenous nucleic acid into the genome of any non-Drosophilidae organism. It also important to note that the age and/or weight of the mice have not been disclosed by the specification. Since the injections of the vectors were done systemically via tail vein, it is assumed that the mice were at least born, at a minimum, and still not at the embryonic developmental stage. As stated above, the art teaches that transgenesis in animals other than mice is highly unpredictable. This applies also to the P-element vector system, even though the transgenic mice created by the claimed method were already delivered (i.e. not in the womb). The difficulty and unpredictability in producing non-mice transgenic species involves significant inventive steps that each adds a level of unpredictability and would place an undue burden of experimentation by a skilled artisan to determine the specific promoter, enhancer, intron, exon, and construct to produce any non-Drosophilidae animal species other than mouse.

Therefore, in view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the claimed invention is not enabled for its full breadth and limiting the scope of the claimed invention to a method of inserting an

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exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-18, and 27-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (U.S. Patent 6,475,798 B2).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

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inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Although the claims of the instant application and said patent are not identical they encompass the same scope, which is a method of inserting an exogenous nucleic acid into the genome of a non-Drosophilae animal using a P-element vector.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.\

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-18, and 27-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Khillan et al. (Developmental Biology, 1985, Vol. 109, pgs. 247-250).

Claims 11-18, and 27-34 are drawn to method of inserting an exogenous nucleic acid into the genome of a non-Drosophilidae animal, wherein said method comprises introducing into said animal a P-element derived vector comprising said exogenous nucleic acid under conditions

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sufficient for transposition to occur and wherein said exogenous nucleic acid is inserted into said genome, a method of inserting an exogenous nucleic acid into the genome of a non-*Drosophilidae* animal, wherein said method comprises introducing into said animal a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is in close approximation to one of the P-element transposase recognized sequences, wherein said vector comprises a transposase domain, wherein said method comprises introducing a second vector comprising a transposase domain into said animal, wherein said animal is a vertebrate, mammalian animal, or rodent, and cells from said animals that have P-element transposase recognized insertion sequences integrated into the genome and cell from said animals that have P-element transposase recognized 31 bp insertion sequences integrated into the genome.

Khillan et al. teach transgenic mice comprising plasmid p π 25.1, which contains the full-length P factor from *Drosophila melanogaster* (pg. 247 col. 1 parag. 2). Khillan continues to teach that said mice were made by micro-injection of said plasmid (linearized) into one-cell mouse embryos (pg. 247 col. 1 last two lines bridge col. 2 lines 1-4). Khillan continues that one newborn from the microinjected embryos was found to carry P element sequences at a concentration of about one copy per mouse genome (pg. 247 col. 2 lines 5-8). Khillan continues that however, integration of P element sequences into the mouse genome was not facilitated by P element transposition but by the pBR322 vector (pg. 249 col. 1 parag. 1 lines 1-6). Khillan continues that one plausible explanation for why the P element did not transposase correctly in the mouse is that the putative transposase, encoded by the P element, was not expressed in the mouse embryo (pg. 249 col. 2 last line bridge pg. 250 col. 1 lines 1-3). Khillan continues that the

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elegance and success of using P element-mediated gene transfer into *Drosophila* prompted them to look for similar P element integration in the mouse (pg. 247 col. 1 parag. 1 last sentence). The method of making transgenic mice taught by Khillan et al. would work in the adult mouse when the transposase activity encoded by the P element was functional unlike the mouse embryo and therefore the claims 11-18 and 27-34 are anticipated by Khillan et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.

The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 1-571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, Ph.D



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